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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,971      03/11/2004      Rudolf Zihlmann      34126/US      5343

25763      7590      07/25/2007

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EXAMINER

MIGGINS, MICHAEL C

ART UNIT

PAPER NUMBER

1772

MAIL DATE

DELIVERY MODE

07/25/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/798,971	ZIHLMANN, RUDOLF	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael C. Miggins	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-17 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-17 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

#### **REJECTIONS WITHDRAWN**

1. All of the 102 and 103 rejections set forth in the non-final rejection of 11/22/06, pages 2-5, paragraphs 1-5 have been withdrawn.

#### **REJECTIONS REPEATED**

2. There are no rejections repeated.

#### **NEW REJECTIONS**

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 6-7, 9-13 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilfong et al. (US 5407713) in view of Cooke (US 5371124).

Wilfong discloses a multi-layered plastic body for storing or conducting a medical, diagnostic pharmaceutical or/and cosmetic product (Fig. 1, abstract, column 37, lines 10-25), said plastic body comprising a first layer made of a stress fracture resistant plastic material (14 from Fig. 1 and column 17, line 5 through column 18, line 20), and at least a second layer, connected to said first layer, and made of a plastic material which exhibits a lower resistance to stress fractures than said first plastic material (16 from Fig. 1 and column 17, line 5 through column 18, line 20) (applies to instant claim 1).

Wilfong discloses wherein the first layer forms an outer layer of the plastic body, thereby forming a skin (Fig. 1 and column 37, lines 10-25), wherein the plastic material of the second layer a lower permeability than the stress fracture layer (since the second layer is more permeable to moisture than the moisture resistant outer layer), wherein the second layer is arranged between the first layer and another layer made of one of the same or another stress fracture resistant plastic material (Fig. 1), wherein the first layer is connected to the second layer through a material and/or positive lock (since layers 14 from Fig. 1 are in direct contact with layer 12 from Fig. 1) (applies to instant claims 6-7 and 10-13).

Wilfong fails to disclose wherein the stress fracture resistant plastic material is semi-crystalline which has a crystalline portion of at least 30%. However, Wilfong does disclose that the stress fracture resistant material of the outer layers is radiation resistant polypropylene (14 from Fig. 1 and column 17, line 5 through column 18, line 20, column 11, lines 10-40).

Cooke discloses a semi-crystalline polypropylene with improved radiation resistant properties in medical articles which has a crystalline portion of at least 30% (abstract, column 2, lines 3-41, column 4, lines 28-38).

Therefore it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have provided the semi-crystalline polypropylene material which has a crystalline portion of at least 30% in the outer layer of Wilfong in order to provide improved radiation resistance as taught or suggested by Cooke.

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5. Claims 2-5 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilfong et al. (US 5407713) and Cooke (US 5371124), as applied to claims 1, 6-7 and 9-13 above, and further in view of Mathur et al. (US 6178832).

Wilfong discloses tubings (column 37, lines 10-25), wherein at least the first layer encloses a hollow space formed by the plastic body (Fig. 1 and column 37, lines 10-25) (applies to instant claim 3).

Wilfong fails to disclose wherein the plastic body is at least part of a container, the container being one of a group comprising ampoules, catheters or components of a fluid handling system, wherein the plastic body comprises at least one opening sealed by a septum and wherein the septum is cast in.

Mathur discloses wherein the plastic body is at least part of a container, the container being one of a group comprising ampoules, catheters or components of a fluid handling system, wherein the plastic body comprises at least one opening sealed by a septum and wherein the septum is cast in (Figs. 9a-9c and column 24, line 30 through column 25, line 58) (applies to instant claims 2-5) for the purpose of preventing fluid/reagent loss from the pouch or entry of contaminants into the pouch.

Therefore it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have provided wherein the plastic body is at least part of a container, the container being one of a group comprising ampoules, catheters or components of a fluid handling system, wherein the plastic body comprises at least one opening sealed by a septum and wherein the septum is cast-in in the pouch of

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Willfong in order to prevent fluid/reagent loss from the pouch or entry of contaminants into the pouch as taught or suggested by Mathur.

Claims 14-17 recite method limitations such as "injection molding" etc. which have little patentable weight since the method by which a part is formed adds no structural limitations to the product claims (MPEP 2113) and thus the prior does not need to disclose applicant's method limitations to read on the claims as written.

### ANSWERS TO APPLICANT'S ARGUMENTS

6. Applicant's arguments filed 5/29/07 have been carefully considered but are deemed unpersuasive. Applicant's arguments with regard to the 102 rejections previously of record are moot since the rejections have been withdrawn.

Applicant has argued that Willfong discloses:

[T]he coextruded multilayered barrier structure 10 according to the present invention should not be subjected to any treatment, such as orientation or stretching, at temperatures above 60°C. Specifically, the employment of such treatment techniques at temperatures above 60°C. would transform the mesophase form of propylene-based materials in the moisture barrier layer 14 of the multilayered structure 10 to **predominantly undesired crystalline form** of propylene-based materials.

And therefore teaches away from using semi-crystalline material. However, Willfong discloses the undesirability of using fully crystalline material but says nothing about semi-crystalline material. Furthermore, Cooke discloses semicrystalline material not fully crystalline material and Cooke does not disclose any treatment above 60 degrees C such as orientation or stretching. Furthermore, Cooke discloses that semicrystalline

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materials result in improved radiation resistance which is a sought after property in Willfong (abstract).

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Miggins whose telephone number is 571-272-1494. The examiner can normally be reached on 1:00-10:00pm.

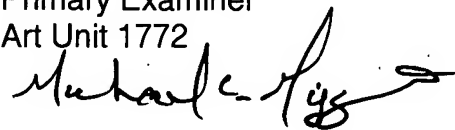
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCM  
July 23, 2007

Michael C. Miggins  
Primary Examiner  
Art Unit 1772

A handwritten signature in black ink, appearing to read "Michael C. Miggins", with a stylized flourish at the end.